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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,522	11/26/2003	Jean-Jacques Codani	GIO-001.01	8678

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FOLEY HOAG, LLP
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EXAMINER

CLOW, LORI A

ART UNIT	PAPER NUMBER
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1631

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication:

Office Action Summary	Application No. 10/723,522	Applicant(s) CODANI ET AL.	
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22,26-35 and 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,26-35 and 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>4/27/05; 3/21/06</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Species of Group A and Group B in the reply filed on 31 October 2006 is acknowledged. The traversal is on the ground(s) that there would be no burden on the Examiner to examine all of the pending claims. This is found persuasive and all claims will be examined. Claims 1-22, 26-35, and 39-46 are currently pending. Claims 23-25, 36-38 have been cancelled.

Priority

Priority to US Provisional Application 60/429,965, filed 29 November 2002 is hereby acknowledged.

Information Disclosure Statement

The Information Disclosure Statement filed 27 April 2004 has been considered in full. The Information Disclosure Statement filed 21 March 2006 has been partially considered. Reference CC has not been considered , as it lacks a publication date. Signed copies of PTO forms 1449 are included with this Office Action.

Drawings

The Drawings filed 26 November 2003 are accepted.

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Specification

The use of the trademarks GenBank and FASTA, for example, have been noted in this application (see page 1). Trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. This is only an example and it is noted that all Trademarks in the specification should be reviewed for compliance.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-22, 26, 27, 32, 33, 35, and 39-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A statutory process must include a step of a physical transformation of matter, or produce a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999))].

Claims 1-22, 26, 27, 32, 33, 35, and 39-46 are directed to a method for “comparing a first sequence and a second sequence” comprising steps that do not include a physical transformation of matter. Therefore, the instant claims encompass non-physical (i.e. *in-silico*) method steps which do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is

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concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful result (i.e. a specific and substantial). In the instant case, the claims do not recite a tangible result such that it is useful to one skilled in the art. For these reasons, the instant claims are not statutory.

In order to expedite prosecution it is suggested that this rejection could be overcome by amending the claims to recite that a result of the method is “displayed” or “outputted” (e.g. output to a user, a display, a memory, or another computer, etc.) (see claims 28-31, and 34), or by amending the claims to include a step of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 26-35, and 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, “associating errors with alignments of the first sequence”. There is insufficient antecedent basis in the claim for “alignments” as no “alignment” has been performed. It is also unclear as to what about the alignment is considered to render an “error”. What constitutes an error? Clarification is requested.

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Claim 2 is unclear, as it is uncertain as to where in the steps of claim 1 this step is to occur. Does it occur before the computation of the percent identity and after the comparing of alignment errors or does it occur after? Clarification is requested.

Claims 3 and 5 recite, "positive matches". It is unclear what is considered a "positive match". Are positive matches ones in which the base or amino acid is the same for each sequence alignment or is some other criteria implemented? Clarification is requested.

Claim 7 recites, "negative matches". It is unclear what is considered a "negative match". Are negative matches ones in which the base or amino acid is not the same for each sequence alignment or is some other criteria implemented? Clarification is requested.

Claim 12 recites, "based on the gaps". There is insufficient antecedent basis in the claim for "the gaps". Clarification is requested.

Claim 13 is unclear, as it is uncertain as to where in the steps of claim 1 this step is to occur. Does it occur before the computation of the percent identity and after the comparing of alignment errors or does it occur after? Does it occur first, before all other steps? Clarification is requested.

Claim 14 recites, "at least one of at least". It is unclear as to what this intended to limit? Does this mean at least one of a polypeptide sequence or a polynucleotide sequence or something else? Clarification through clearer claim language is requested.

Claims 17 and 45 recite, "associating errors includes computing a string edit distance". It is unclear what about a string edit distance associates errors? Clarification is requested.

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Seguritan (Reference CD, incorrectly listed as Dawson on PTO Form 1449).

The instant claims are drawn to comparing a first sequence and a second sequence by associating errors in alignments, computing percent identities, and identifying mismatches.

Seguritan teaches sequence inputs from directory files, mismatch identification using an algorithm, and percent identity matching using an algorithm (pages 4-5). The sequences are DNA sequences, as in claim 14. Seguritan teaches output of data at page 6. Therefore Seguritan anticipates claims 1-3, 14, 28, 29, and 31.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

January 7, 2007

Lori A. Clow, Ph.D.

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Lori A. Clow
Patent Examiner

1/7/07